

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-5, 9, 12-18, 20-21 and 24-32 and 34-39 are pending in the application, with 1, 12, 14-16, 27, 28 and 34 being the independent claims. Claims 1-5, 9, 12-18, 20, 21, 24-27, and 34-39 have been withdrawn. Claim 28 is sought to be amended. Applicants reserve the right to file one or more continuation applications directed to the subject matter of the canceled claims.

II. The Amendments

Claim 28 has been amended so that the claim is no longer directed to a method of preventing diabetes in a subject at risk of developing diabetes. Claim 28 has been further amended to recite that the protein having 90% identity to galectin-3 is a protective diabetes-mediating protein *that ameliorates symptoms of diabetes in said subject*. Support for this amendment can be found, *inter alia*, in the specification at page 2, lines 12-18.

It is believed that these changes introduce no new matter and that the claims are now in better condition for appeal. A Notice of Appeal is being filed concurrently with this Amendment and Reply. Accordingly, prompt entry of these after-final amendments is respectfully requested.

III. The Rejections

A. The Indefiniteness Rejection

At page 2 of the Office Action, the Examiner has rejected claims 28-32 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner contends that it is not clear whether the "protective diabetes mediating protein" recited in the claims has the activity of protecting the diabetes mediating state or has protective activity against diabetes. Applicants respectfully traverse the rejection.

Applicants disagree with the rejection. There is nothing indefinite about claim 28. What is intended by a "protective" diabetes mediating protein is very clearly defined in Applicants' specification. At page 2, lines 12-16, the application teaches that: "A protective diabetes-mediating protein ("protective protein") is characterized as a protein capable of protecting against the development of diabetes and/or delaying the onset of diabetes in a subject at risk for development of diabetes, or ameliorating the symptoms of diabetes in a subject suffering from diabetes." Given this very precise definition of the term "protective diabetes-mediating protein" in the specification, it is unclear why the Examiner considers the claim indefinite. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

B. The Written Description Rejection

At page 3 of the Office Action, the Examiner has rejected claims 28-32 under 35 U.S.C. § 112, first paragraph, on the ground that the specification does not reasonably convey to one of ordinary skill in the art that Applicants had possession of the claimed

subject matter at the time the application was filed. Specifically, the Examiner contends that: "The specification does not describe a method of *preventing* a diabetes state in a subject comprising administering to said subject a protein variant comprising amino acid sequence that has at least 90% (claim 28) or 95% (claim 30) sequence-identity to the full-length sequence of SEQ ID NO:4 (human galectin-3)." The Examiner further asserts that "the specification does not teach the variant protein has activity ameliorating or preventing a diabetes state." Applicants respectfully traverse the rejection.

Without acquiescing in the propriety of the rejection, and solely in the interests of expediting prosecution, Applicants have amended claim 28 so that it no longer encompasses methods of *preventing* diabetes in a subject at risk of developing diabetes. Moreover, Applicants have further amended claim 28 to specify that the protein having at least 90% sequence identity to human galectin-3 (SEQ ID NO:4) is a protective diabetes mediating protein *that ameliorates symptoms of diabetes in said subject*.

Applicants emphasize that the amended claims encompass a very specific group of proteins that all share a *common function* (*i.e.*, they all ameliorate symptoms of diabetes in the subject) as well as a *common structural relationship* (*i.e.*, homology to human galectin-3). The specification also describes with particularity what constitutes a protective diabetes-mediating protein, as well as assays for identifying and isolating such protective diabetes-mediating proteins. (Application at page 17, lines 8-15, and pages 24-26.)

Accordingly, Applicants are in possession of the necessary common attributes possessed by members of the claimed genus of protective diabetes-mediating proteins. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

B. The Enablement Rejection

At page 4 of the Office Action, the Examiner has maintained the rejection of claims 28-32 under 35 U.S.C. § 112, first paragraph, on the ground that they encompass subject matter which is not described in the specification in a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse the rejection.

Applicants note that the Examiner's basis for making this rejection is that the claims are not enabled only to the extent they encompass methods of *preventing* the occurrence of diabetes in a subject. The Examiner does not appear to have a concern with the claims to the extent they relate to methods of treating symptoms of diabetes. Indeed, the Examiner expressly acknowledges this in the Office Action at page 6: "The current invention enables a method of ameliorating or treating diabetes, but NOT preventing the diabetes."

Without acquiescing in the propriety of the rejection, and solely in the interests of expediting prosecution, Applicants have amended claim 28 so that it no longer encompasses method of preventing diabetes in a subject. Accordingly, the basis for the rejection has been obviated. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

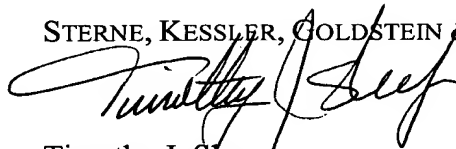
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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